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EXAMINER	
REIDEL, JESSICA L	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 06/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

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Office Action Summary	**Application No.** 10/680,528	**Applicant(s)** DENO ET AL.	
	Examiner Jessica L. Reidel	**Art Unit** 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-34 and 61-89* is/are pending in the application.

4a) Of the above claim(s) *1-3,13-15 and 25-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-6, 9-12, 16-18, 21-24, 29, 31-34, 61-64, 70-73, 79-84* is/are rejected.

7)☒ Claim(s) *7,8,19,20,30,65-69,74-78 and 85-89* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date *02/05 04/06*.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Claims 4-12, 16-24, 29-34 and 61-89 in the reply filed on June 2, 2006 is acknowledged. The traversal is on the ground(s) that "there is no undue burden imposed on the Examiner to examine the subject application as originally filed". This is not found persuasive because the groups of inventions (as defined in the Restriction Requirement of May 2, 2006) were found to be distinct, shown by their separate classifications, separate statuses in the art and different fields of search, thusly imposing an undue burden on the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Specification

2. The abstract of the disclosure is objected to because of its language use. The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," "are disclosed," etc. Correction is required. See MPEP § 608.01(b).

3. The disclosure is objected to because of the following informalities: the section marked "CROSS REFERENCE TO RELATED APPLICATIONS" is replete with inadvertent errors and should be updated with the appropriate serial numbers of each application listed, as well as with the current status of each application listed. Appropriate correction is required.

Claim Objections

4. Claims 7, 19, 65, 74 and 85 are objected to because of the following informalities: the language is awkward and confusing. As to Claims 7 and 65, the Examiner suggests revision of lines 3-5 to read, "the method further comprising delivering an extra-systolic pulse at the expiration of the extra-systolic interval after detection of a systolic depolarization of the heart during cardiac cycles in which a probe pulse is not delivered." As to Claims 19 and 74, the Examiner suggests revision of the last lines of the claims to read, "and controls delivery of an extra-systolic pulse, wherein the extra-systolic pulse is delivered at the expiration of the extra-systolic interval after detection of a systolic depolarization of the heart during cardiac cycles in which a probe pulse is not delivered." As to Claim 85, the Examiner suggests revision of the last two lines of the claim to read, "extra-systolic pulses at the expiration of the extra-systolic interval after detection of a systolic depolarization of the heart during cardiac cycles in which a probe pulse is not delivered." Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 4-5, 16-17, 29, 61-63, 70-72 and 79-83 are rejected under 35 U.S.C. 102(b) as being anticipated by Bennett et al. (U.S. 5,213,098) (herein Bennett). Bennett discloses a post-

extra-systolic potentiation (PESP) cardiac pacing energy stimulator 34 for applying paired and/or triggered pacing stimulation pulses, read as extra-systolic stimulation to the right atrium and/or ventricle (see Bennett Abstract and column 2, lines 1-9). Bennett specifies that the stimulator 34 performs a method of providing post-extra-systolic potentiation effects to augment filling of the ventricular chambers of the heart comprising the steps of providing pacing stimuli on demand to the atrium of the heart and extra-systolic stimulation timed from an immediately preceding pacing pulse or sensed atrial depolarization (read as a systolic depolarization) that is sufficient to effect post-extra-systolic potentiation of the atrium while falling within the refractory period of the ventricle (see Bennett column 4, lines 41-53). Bennett further teaches that a parameter for delivery of such extra-systolic stimulation, namely the paired or coupled pulse interval (irrelevant of whether the first pulse in the pair/couple is a pacing pulse or systolic depolarization), read as the extra-systolic interval is dependant on the refractory interval and Bennett further discloses that the algorithm used by the stimulator 34 may include a self-checking feature that determines the effective atrial and ventricular refractory periods as disclosed by Baker, Jr. et al. (U.S. 4,280,502) (herein Baker, Jr.) (see Bennett column 14, lines 4-9). Baker, Jr. discloses that the refractory interval of the heart adjacent a sensing electrode may be determined by a first search routine which comprises the steps of (see Baker, Jr. Abstract and column 3, lines 28-44) delivering a probe pulse to the heart at various times in the interval between the end of the minimum interval and a tachycardia signal and determining whether the probe pulse captured the heart by detecting whether delivery of the probe pulse resulted in stimulation of the cardiac tissue, read as an evoked response (see Baker, Jr. column 5, lines 46-60 and column 6, lines 13-19).

7. Claims 61-64, 70-73 and 81-84 are rejected under 35 U.S.C. 102(e) as being anticipated by Burnes et al. (U.S. 2004/0220631) (herein Burnes).

The applied reference has a common Inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

8. As to Claims 61, 70 and 81, Burnes discloses an microprocessor-controlled implantable system and method for delivering extra systolic stimulation pulses at an extra systolic interval based on a detected recovery time, read as a refractory period to effectively produce post-extra systolic potentiation while preventing delivery of extra systolic stimuli during the vulnerable period (i.e. during the time when the tissue is refractory) (see Burnes Abstract). Burnes discloses a method comprising measuring a delay between delivery of a probe pulse to a heart and detection of an evoked response resulting from delivery of the pulse and adjusting an extra-systolic interval (ESI) for delivery of extra systolic stimulation (ESS) to the heart based on the delay (see Burnes Fig. 6A and page 9, paragraphs 88-91). Burnes further discloses the method 800 employs an approximate measure of the end of local refractory to set an extra systolic interval (ESI) used during extra systolic stimulation (ESS) comprising at step 802 delivering ESS pulses at decreasing ESIs until loss of capture and at step 804 storing end refractory as the last pulse interval at which capture was lost. Burnes further discloses that at step 806, the ESI to be

applied during ESS therapy is set equal to the end refractory time plus a safety interval (see Burnes Fig. 6B and page 9, paragraph 94).

9. As to Claims 64, 73, and 84, Burnes further discloses that the measured delay (i.e. ARI) is compared to the local end refractory time, read as a threshold value (see Burnes Fig. 6A and page 9, paragraphs 88-91).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 9-12, 21-24 and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bennett. As to Claims 9-10, 21-22 and 31-32, Bennett discloses the claimed invention as discussed above except that it is not specified that if the probe pulse captures the heart, the interval for subsequent delivery is decreased. It would have been obvious to one having ordinary skill in the art a that the time the invention was made to modify the method as taught by Bennett with the steps of determining that the probe pulse captured the heart and decreasing the interval for delivery of a subsequent probe pulse since it was known in the art that the shorter and shorter the interval used.for delivery of such pulses, eventually loss of capture will occur because the probe pulse will be delivered within the refractory interval and the interval used just before the interval where the loss of capture occurred is a reliable approximation of the refractory interval.

12. As to Claims 11-12, 23-24 and 33-34, Bennett discloses the claimed invention as discussed above except that it is not specified that if the probe pulse does not capture the heart,

the interval for subsequent delivery is increased. It would have been obvious to one having ordinary skill in the art a that the time the invention was made to modify the method as taught by Bennett with the steps of determining that the probe pulse did not capture the heart and increasing the interval for delivery of a subsequent probe pulse, since it was known in the art that the longer and longer the interval used for delivery of such pulses, eventually capture will occur because the probe pulse will be delivered outside of the refractory interval and the interval used just before the interval where the capture occurred is a reliable approximation of the refractory interval.

13. Claims 6 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bennett in view of Ecker et al. (U.S. 5,702,427) (herein Ecker). Applicant differs from Bennet in that the determination of whether the probe pulse captures the heart includes monitoring the intracardiac pressure and determining whether the probe pulse captured the heart based on a rate of change of the intracardiac pressure subsequent to delivery of the probe pulse. The Examiner considers this type of capture determination to be conventional and well known in the art with Ecker being but one example (see Ecker Abstract, column 4, lines 50-67, column 5, lines 1-24 and columns 6-7).

Allowable Subject Matter

14. Claims 8, 20, 30, 66-69, 75-78 and 86-89 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. Claims 7, 19, 65, 74 and 85 would be allowable if rewritten to overcome the objections, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. Burnes et al. (U.S. 2004/0220640) discloses a method and apparatus for determining myocardial electrical restitution and controlling extra systolic stimulation.

17. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The Examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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